**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| UNITED STATES OF AMERICA | ) | |
| v. | ) | No. 17-cr-10288-WGY |
| AEGERION PHARMACEUTICALS, INC., | ) | |
| Defendant. | ) | |

**GOVERNMENT'S SENTENCING MEMORANDUM**

Aegerion Pharmaceuticals, Inc. ("Aegerion" or "Defendant") intends to plead guilty to two counts of misdemeanor misbranding of its drug, Juxtapid, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1). The United States asks the Court to fine Aegerion $7.2 million, paid over three years in light of Aegerion's financial limitations, and to impose a three- to five-year term of probation, on such terms as the Court deems appropriate, but including, at minimum, an anti-disparagement provision. This recommended sentence is consistent with the plea agreement executed by the parties under Federal Rule of Criminal Procedure 11(c)(1)(B).

Aegerion's guilty plea results from a four-year investigation into Defendant's misbranding of its drug, Juxtapid. In pleading guilty, Aegerion will take responsibility for criminal conduct orchestrated by former executives and managers whom Defendant purged from the corporation before it offered to plead guilty. Consistent with the misdemeanor charges in the Information, Aegerion will not admit to an intent to defraud or to mislead. Defendant has cooperated and pledged continuing cooperation with the government's investigation of the former management responsible for Defendant's past criminal conduct.

Aegerion's guilty plea is part of a global resolution comprising:

1. A corporate integrity agreement with the U.S. Department of Health and Human Services, Office of Inspector General;

2. A Consent Decree to be monitored by the Food and Drug Administration ("FDA") to ensure compliance with the Food, Drug, and Cosmetic Act;

3. A three-year Deferred Prosecution Agreement ("DPA") with the United States concerning a corporate conspiracy at Aegerion to violate the Health Insurance Portability and Accountability Act ("HIPAA"); and,

4. A civil settlement of a parallel *qui tam* action, *United States ex rel. Clarke, et al. v. Aegerion Pharmaceuticals, Inc.*, No. 13-cv-11785-IT (D. Mass.) that will provide $28 million (plus interest) in restitution to federal programs harmed by Aegerion's former sales practices.

In this context, and considering that Juxtapid is one of the few cholesterol-lowering drugs that works in patients who really have the rare disease (homozygous familial hypercholesterolemia ("HoFH")) for which the FDA approved Juxtapid as a treatment, the proposed sentence satisfies the requirements of 18 U.S.C. § 3553. The United States requests that the Court accept Aegerion's guilty plea and the parties' joint sentencing recommendation, as laid out in the parties' plea agreement.

## I. SUMMARY OF FACTS

### A. The Development of Juxtapid (Lomitapide)

Juxtapid (generic: lomitapide) inhibits the production of low-density lipoprotein cholesterol ("LDL-C"), often called the "bad" cholesterol due to its association with cardiovascular disease. When properly managed, treatment with Juxtapid can dramatically lower LDL-C levels, even in patients who do not respond to other therapies, such as statin therapy. However, due to its side effects (*e.g.*, liver toxicity and severe gastrointestinal distress), Juxtapid, despite its efficacy, has never been considered appropriate for use in the general population.

In 2007, Aegerion obtained commercial development rights for Juxtapid from the University of Pennsylvania, where a team of scientists had been studying its potential therapeutic

use. By that time, the FDA had indicated to University of Pennsylvania scientists that existing and proposed clinical studies of Juxtapid would not be sufficient to allow the FDA to approve Juxtapid for the treatment of severe hypercholesterolemia in general. The FDA accepted, however, that the drug could have potential for treatment of high cholesterol in patients with HoFH, a rare genetic disease inherited from both parents. According to Aegerion's pre-approval submissions to an FDA advisory committee, as a result of genetic defects, "patients with HoFH develop dramatically early and severe atherosclerotic CVD [cardiovascular disease] and often, early cardiac-related death. Symptomatic CVD often presents during the first 2 decades of life [for HoFH patients], and includes atherosclerosis in the coronary arteries, the carotid arteries, the aorta and aortic valve, and the peripheral vasculature, often leading to heart attack, stroke, and death. . . . If untreated, most HoFH patients do not survive past age 30 due to death from CVD" (citations omitted).[1] In its submissions to the FDA, Aegerion cited historical studies estimating the prevalence of HoFH as one per million (*i.e.*, roughly 300 people in the United States).

In 2009, notwithstanding the FDA's previously stated position, Aegerion asked the FDA whether it could develop Juxtapid for treatment of high cholesterol in patients with HoFH *or* with refractory heterozygous familial hypercholesterolemia ("HeFH"), a typically less severe form of hypercholesterolemia than HoFH that is inherited from only one parent.[2] The FDA told Aegerion that such an expanded indication would require additional clinical study, including potentially an outcomes study (*i.e.*, to determine if use of Juxtapid affects cardiovascular risk).

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[1] Sponsor's Background Package, NDA #203858 (https://wayback.archive-it.org/7993/20170405220241/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM323843.pdf.

[2] HeFH has been estimated to affect as many as 620,000 patients in the United States. "Refractory" HeFH is HeFH that does not respond adequately to other treatments.

By 2010, Aegerion appeared to reverse course and told the FDA it would only seek approval for HoFH, due to financial constraints.

In June 2011, Aegerion met with the FDA about obtaining approval for Juxtapid only for HoFH. The FDA agreed that Aegerion's existing 29-person clinical study was sufficient for potential approval for treatment of HoFH patients, but the FDA specifically rejected an Aegerion proposal to define HoFH in a manner that would overlap with severe HeFH and allow for HoFH diagnoses without respect to parental history *at all*. The FDA told Aegerion—and Aegerion's senior management, including its then chief executive officer, acknowledged—that the FDA expected Juxtapid's indication population to align with the strict and narrow diagnostic standards Aegerion used to identify HoFH patients for its own clinical trial. After June 2011, Aegerion never again told the FDA that it intended to define HoFH to overlap broadly with other forms of hypercholesterolemia.

In December 2012, after lengthy negotiations and discussions with Aegerion, the FDA approved Juxtapid with the following indication: "an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)." The approved label contains the following information:

- "The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH."
- "The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined."
- "Pediatric Patients: Safety and effectiveness not established."

The approved label also includes a boxed warning regarding the known risk that Juxtapid can cause liver toxicity.

The FDA also required Aegerion to implement a Risk Evaluation Mitigation Strategy ("REMS") program under which, among other things, Aegerion had to educate prescribers about Juxtapid's narrow indication and risk of liver toxicity, to limit prescription processing to a single pharmacy, and to require prescribers to enroll in the REMS program. The REMS program required prescribers to attest that each patient "has a clinical or laboratory diagnosis consistent with HoFH." The REMS program also required Aegerion to file certain reports and data with the FDA regarding implementation of the REMS program itself.

B. Aegerion's Misbranding of Juxtapid

Aegerion began selling Juxtapid in January 2013. That same month, Aegerion's sales management implemented a commercial strategy aimed at blurring the definition of HoFH to include not only HeFH but also treatment-resistant high cholesterol generally. Aegerion focused its commercial message on "not defining" HoFH. Aegerion soon found that lipidologists and other specialists were not receptive to its message that HoFH cannot be defined; Aegerion then refocused its marketing on so-called community cardiologists and nurse practitioners who were less familiar with HoFH. Aegerion's sales force marketed Juxtapid for treating patients not diagnosed with HoFH and whose clinical profiles did not align with any established clinical diagnostic criteria for HoFH, let alone the strict and clear diagnostic criteria Aegerion itself used to identify HoFH patients for its pre-approval clinical study of Juxtapid.[3] Aegerion thus marketed Juxtapid for the treatment of general hypercholesterolemia, often based on the unsupported claim that Juxtapid takes patients "out of harm's way"—all despite the warning on

[3] Misconduct by Aegerion's sales personnel was not limited to the crimes charged in the Information. As Aegerion has admitted in connection with its DPA with the United States, Aegerion, by and through its sales management and sales force, conspired to violate HIPAA by gaining unauthorized access to individually identifiable health information held by HIPAA-covered entities, all for the purpose of marketing Juxtapid for Aegerion's commercial advantage.

Juxtapid's label that "[t]he effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined."

As further charged in the Information, Aegerion's sales and marketing strategies also failed to comply with Aegerion's obligations under the Juxtapid REMS program, which was designed specifically to educate prescribers about the risks of liver toxicity and to reinforce Juxtapid's narrow indication.

C. Company Culture

Aegerion's corporate culture substantially caused the illegal conduct described above. Aegerion's then president directly taught the sales force the "Art of Not Defining HoFH." In 2013, Aegerion's then chief executive officer described Juxtapid as a drug suitable for children (despite lacking FDA approval for pediatric use) and for reducing cardiovascular risk (despite the clear statement on Juxtapid's label that such effect had not been determined). By mid-summer 2013, Aegerion received multiple internal complaints about pressure from sales management to market Juxtapid illegally. In November 2013, the FDA issued a Warning Letter to Aegerion, expressly repudiating claims by Aegerion's then chief executive officer that Juxtapid reduces the risk of heart attacks. Yet illegal conduct continued at Aegerion in 2014. In October 2014, in response to government inquiries, Aegerion disciplined roughly half of its sales force for explicitly promoting Juxtapid for HeFH and "severe refractory" lipid patients in addition to HoFH patients.

D. Aegerion's Cooperation

The United States understands that the Aegerion Board of Directors only fully became aware of the details of the government's investigation in early 2015. Aegerion then changed course. It conducted a new internal investigation. In late summer 2015, Aegerion removed its

then chief executive officer and its then chief operating officer. In September 2015, Aegerion informed the government that it would cooperate with the ongoing investigation. By early 2016, new senior management was in place at Aegerion, and the company informed the government that, in addition to cooperating with the United States' investigation of individuals, Aegerion would plead guilty to charges under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Aegerion has cooperated with the government since that time. Aegerion's purge of its sales management and commercial team continued throughout 2016 and 2017.

E. The Global Resolution

In late spring 2016, Aegerion's new management and the United States reached an agreement in principal for a global resolution of all outstanding investigations of Aegerion, including the Department of Justice's criminal and civil investigations and the Securities and Exchange Commission's ("SEC") parallel investigation.[4] Ultimately, the global resolution includes: (a) guilty pleas to misdemeanor misbranding charges; (b) a DPA on a conspiracy to violate HIPAA (before Judge Richard Stearns in *United States v. Aegerion Pharmaceuticals Inc.*, No. 17-cr-10289 (D. Mass.)); (c) a Consent Decree of Permanent Injunction (before Judge Mark Wolf in *United States v. Gerrits, et al.*, No. 17-cv-11818 (D. Mass.)); (d) payment of damages and resolution of the *qui tam* (before Judge Indira Talwani, *United States ex rel. Clarke, et al. v. Aegerion Pharmaceuticals, Inc.*, No. 13-cv-11785 (D. Mass.)); and (e) a Corporate Integrity Agreement related to the *qui tam*.

In spring 2016, the Department of Justice received detailed information from Aegerion regarding its business performance and financial resources and ultimately determined that

[4] The resolution does not include investigations related to possible violations of the Foreign Corrupt Practices Act.

Aegerion could afford to pay roughly $35 million over time in fines, penalties, and damages related to the Department's multiple investigations.[5] The United States agreed to the resolution with the understanding that the agreement in principal would allow Aegerion to seek investors to help it survive. Aegerion subsequently became part of Novelion Therapeutics, which has used its financial resources to maintain Aegerion's operations.

## II. PLEA AGREEMENT AND SENTENCING RECOMMENDATION

Aegerion has executed a plea agreement covering the misconduct described above. Defendant has agreed to plead guilty to two counts of misdemeanor misbranding, not requiring it to admit an intent to defraud or to mislead; to cooperate with the government's investigation of culpable individuals, including Aegerion's former senior management; and to recommend that it pay a criminal fine of $7.2 million over three years.

### A. Criminal Fine and Application of the Sentencing Guidelines

The Statutory Index to the Sentencing Guidelines indicates that the guideline for misdemeanor violations of the FDCA, 21 U.S.C. §§ 331(a) and 333(a)(1), is U.S.S.G. § 2N2.1, which has a base offense level of 6.

The fine guidelines in Chapter 8, U.S.S.G. §§ 8C2.2 through 8C2.9, apply to "each count for which the applicable guidelines offense level is determined under" the subsections listed in U.S.S.G. § 8C2.1. Section 2N2.1 is not listed under § 8C2.1(a) or (b).[6] *See also* Thomas W.

[5] The SEC's investigation and settlement were separate and separately handled and negotiated; however, the Department of Justice understands from Aegerion that the criminal resolution with Aegerion was a threshold requirement for the rest of the global resolution.

[6] Application Note 2 of U.S.S.G. § 8C2.1 adds an additional category of cases where the fine guidelines of §§ 8C2.2 through 8C2.9 apply: if the offense guideline from Chapter Two applicable to the defendant's conviction is not set forth in subsections (a) or (b), but that offense guideline results in the determination of the offense level by use of one of the guidelines in those subsections. The application note gives as an example the situation "where the conduct set forth

Hutchison, *et al.*, *Federal Sentencing Law and Practice*, § 8C2.1 (2017 ed.) ("The categories of cases not included in [USSG § 8C2.1] subsection (a), and to which the provisions of §§ 8C2.2 through 8C2.9 do not ordinarily apply, include . . . food and drug offenses."). Accordingly, the fine guidelines of Chapter 8 do not apply an organization convicted of a misdemeanor FDCA violation,[7] and the Court should apply the provisions of 18 U.S.C. §§ 3553 and 3572 to determine an appropriate fine.

The maximum fine provided by statute for a misdemeanor violation of the FDCA by an organization is the greatest of: (1) the amount specified in the law setting forth the offense (here, $1,000, under 21 U.S.C. § 333(a)(1)); (2) $200,000; (3) twice the gross pecuniary gain derived by the organization from the offense; or (4) twice the pecuniary loss suffered by another person because of the offense. *See* 18 U.S.C. § 3571(c) and (d).

The calculation of Aegerion's pecuniary gain from the charged conduct has been challenging. Many relevant patient files do not include diagnoses of HoFH, and many patient files that include the diagnosis lack information aligning patients with established clinical standards for diagnosing HoFH. Ultimately, to estimate Aegerion's pecuniary gain, the government used Aegerion's internal sales data, which includes clinical information about

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in a count of conviction ordinarily referenced to § 2N2.1 . . . establishes §2B1.1 . . . as the applicable guideline." Under § 2N2.1(c)(1), § 2B1.1 applies if the offense "involved fraud," but this subsection does not define that phrase. Misdemeanor violations of the FDCA do not include as an element an intent to defraud or mislead. *Compare* 21 U.S.C. § 333(a)(1) *with* 21 U.S.C. § 333(a)(2). In addition, Application Note 1 of U.S.S.G. § 2N2.1 indicates that the usual application of this guideline "assumes a regulatory offense that involved knowing or reckless conduct." As Aegerion is agreeing to plead guilty to a count of conviction that does not itself involve fraud, the parties agreed to recommend the ordinary use of § 2N2.1 for sentencing. Thus, § 8C2.10 applies instead of §§ 8C2.2 to 8C2.9.

[7] In addition, Application Note 2 of U.S.S.G. § 8A1.2 directs that the adjustments in Chapter Three, Parts A, B, C, and E do not apply to organizations.

patients, but, crucially, does not include information about patients' family history. That omission is consistent with Aegerion's sales messaging that maternal and paternal history of hypercholesterolemia is not necessarily part of clinical diagnosis of HoFH, which, by definition, is inherited from both parents. Without information about parental history, the government used an alternative metric based on widely accepted and used clinical diagnostic criteria for familial hypercholesterolemia generally, with the goal of identifying facially non-HoFH patients.[8]

In the Information, the United States alleges a pecuniary gain of not less than $15,451,827. This amount derived from the analysis of Aegerion's internal sales data described above. The United States now calculates the pecuniary gain to be at least $15,764,320. This figure is based on revised calculations of the average payments received for Juxtapid shipments, adjusted by Aegerion's gross margin on the drug.[9]

Under U.S.S.G. § 8C3.3(b) and based on an analysis of Aegerion's finances conducted before Novelion acquired it in November 2016, there is a basis for a reduction in the fine on account of Aegerion's independent inability to pay and the public health need for Aegerion to continue supplying U.S. HoFH patients with Juxtapid.[10] Having agreed in principle to a suggested fine payment schedule with Aegerion in May 2016, the government has not reassessed Aegerion's ability to pay since Novelion acquired it. However, based on Defendant's

[8] The Pre-Plea Presentence Report (¶¶ 31-32) discusses the government's method.

[9] The government's pecuniary gain calculation focuses on the pecuniary gain from Count I of the Information. The pecuniary gain from Count II may derive from this same set of prescriptions; however, the government lacks information to assess the pecuniary gain from certain offense conduct underlying Count II. The United States therefore recommends that the Court assess pecuniary gain as proposed in the parties' plea agreement.

[10] This conclusion would be the same if the Court were to apply § 2B1.1 such that the amount from the offense level fine table in § 8C2.4(a)(d) exceeded Aegerion's pecuniary gain, as the resultant minimum guidelines fine would be greater than that calculated using pecuniary gain.

representations made to the government and to the Probation Office (as reflected in the Pre-Plea Presentence Report at ¶¶ 76-81), the government believes that the recommended criminal fine of $7.2 million remains appropriate, as discussed further below.

B. Restitution

The United States is committed to ensuring that any victims of Aegerion's crimes are fully and fairly recompensed for their economic losses. Despite the government's best efforts, however, it cannot currently state with sufficient certainty which patients and private payors were victims of Aegerion's misbranding efforts and the economic extent to which they were harmed for purposes of restitution.

Many patients were covered by public payors, such as Medicare, that will receive reimbursement of paid costs through the civil settlement between the government and Aegerion. Private payors that covered Juxtapid often had detailed prior authorization processes in which clinical reviewers determined if the payor would cover a Juxtapid prescription. Those prior authorizations typically required a positive diagnosis of HoFH and documentation corresponding to established clinical diagnostic standards. The prior authorization processes should have filtered out off-label prescriptions generated by Aegerion's marketing scheme; to the extent apparent off-label prescriptions made it past payors' review processes, the government cannot link resulting payments made by payors to Aegerion's efforts to misbrand Juxtapid.

The determination of appropriate restitution for patients is complicated because restitution is limited to certain actual economic losses, directly and proximately caused by the offense conduct. *See United States v. Olson*, 867 F.3d 224, 229-30 (1st Cir. 2017) ("We have previously held that two 'bedrock principles' of restitution orders require . . . that the government 'show not only that a particular loss would not have occurred but for the conduct underlying the

offense of conviction, but also that the causal connection between the conduct and the loss is not too attenuated (either factually or temporally).'") (citing *United States v. Cutter*, 313 F.3d 1, 7 (1st Cir. 2002)); *cf. United States v. Innarelli*, 524 F.3d 286, 294–95 (1st Cir. 2008) ("[T]he district court may not take into account the emotional impact of the [crime] in calculating an MVRA restitution award."). The United States believes that Juxtapid patients generally had insurance that covered out-of-pocket costs, except for co-payments. (Patients usually could not afford out-of-pocket costs of roughly $26,000 per month.) The government lacks information about those co-payment amounts, but Aegerion may be able to provide such information.

The United States submits that it may be exceedingly difficult to craft a restitution order with respect to economic losses from physical harm to patients directly and proximately caused by Aegerion's misbranding of Juxtapid. According to Aegerion's data, numerous patients suffered adverse events from the use of Juxtapid, typically elevated liver enzymes (which could eventually lead to liver damage) or gastrointestinal distress (*i.e.*, diarrhea). The government does not know how to identify physical harm and resulting economic harm caused by liver enzyme elevations. Relatedly, although economic harm from gastrointestinal distress directly and proximately caused by off-label use of Juxtapid is possible (*e.g.*, missed work), the government presently lacks information to determine the existence of any such harm.

If the Court were to establish a process for gathering necessary patient information to allow for possible restitution to patient victims, the government would recommend implementing the process described in the appendix to the plea agreement and will provide the Court any assistance it can.

## III. THE SENTENCING RECOMMENDATION IS REASONABLE AND WARRANTED UNDER THE CIRCUMSTANCES OF THIS CASE

The government believes that its sentencing recommendation is reasonable and satisfies the applicable factors under 18 U.S.C. § 3553. The recommended sentence effectively punishes Aegerion for serious criminal conduct directed by its former management, and it prevents further wrongdoing given the recommended term of probation, as well as Aegerion's numerous compliance obligations under the FDA Consent Decree and the DPA. Further, the recommended sentence requires Aegerion not to deny that it committed the crimes of conviction, and thus provides significant general deterrence. The criminal fine takes into consideration the factors enumerated in 18 U.S.C. § 3572, including Aegerion's income, earning capacity, and financial resources; the relative burden of the fine; the need to deprive Aegerion of illegally obtained gains; and the company's size and remedial measures. Moreover, based upon the Department of Justice's "ability to pay" analysis, a criminal fine of $7.2 million and the parallel civil settlement of $28 million represent the top end of what Aegerion could afford at the time that Aegerion agreed to plead guilty to the charged offenses. Finally, the recommended sentence appropriately recognizes that Aegerion's current corporate parent, Novelion, did not cause the offenses of conviction, and the government has no information that Novelion has engaged in similar misbranding of Juxtapid.

## IV. CONCLUSION

For the above-stated reasons, the United States requests that the Court impose sentence as recommended in the parties' plea agreement and sentence Aegerion to a criminal fine of $7.2 million and a term of probation of three to five years.

Dated: January 26, 2018

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that I filed the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to all attorneys of record.

By: /s/Kriss Basil
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